ATTORNEY DOCKET NO. 5656.34 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ideker et al.
Serial No.: 10/727,123
Filed: December 2, 2003
Confirmation No. 4773
Examiner: Eric D. Bertram
Group Art Unit: 3766
For: **METHODS, SYSTEMS AND COMPUTER PROGRAM PRODUCTS TO INHIBIT VENTRICULAR FIBRILLATION DURING CARDIOPULMONARY RESUSCITATION**

May 24, 2007

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APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. § 41.67

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed March 26, 2007 and in response to the Notice of Panel Decision dated April 24, 2007.

Real Party In Interest

The real party in interest is assignee University of Alabama Research Foundation.

Related Appeals and Interferences

Appellants are aware of no appeals or interferences that would be affected by the present appeal.

Status of Claims

Claims 1-25 are canceled. Claims 29, 30, 34-40, 46-48, 50, 53, 58 and 59 are withdrawn from consideration as being drawn to a non-elected invention and species. Claims 26-28, 31-33, 41-45, 49, 51, 52 and 54-57 are pending and stand rejected.

Appellants appeal the final rejection of Claims 26-28, 31-33, 41-45, 49, 51, 52 and 54-57 by the Final Office Action dated November 24, 2006 ("the Final Action") as confirmed in the Advisory Action dated March 8, 2007 ("the Advisory Action").

Status of Amendments

No amendments have been made after the Final Action.

Summary of Claimed Subject Matter

The independent Claim 26 recites a method for performing chest compression during cardiopulmonary resuscitation (CPR). The method includes sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR. *Specification*, page 8, lines 9-11; block **130**, **Figure 3**. A vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject is identified, and the heart of the subject is compressed during a non-vulnerable portion of the spontaneous intrinsic cardiac cycle based on the identifying step, thereby inhibiting reinduction of fibrillation and/or improving cardiac function. *Specification*, page 8, lines 11-20; blocks **132, 134, 136**; **Figure 3**.

The independent Claim 41 recites a system for performing chest compression during cardiopulmonary resuscitation (CPR). The system includes means for sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR (block **130**, **Figure 3**, (*Specification*, page 9, lines 9-11); a "cardiac activity sensor" **30** in **Figures 6-7** and **9** (*Specification*, page 10, lines 10-12); an "implantable defibrillator with cardiac sensor" **90I** in **Figure 8** (*Specification*, page 10, lines 20-22); a "favorable cardiac compression timing module" **450** in **Figure 10** (*Specification*, page 13, line 5-8)); means for electronically identifying a favorable time to compress the chest to avoid a vulnerable portion of a spontaneous intrinsic cardiac cycle of the subject based on the sensed parameter (block **132, 134, 136**, **Figure 3** (*Specification*, page 9, lines 11-20); a "cardiac activity sensor" **30** in **Figures 4A-4B, 6-7** and **9** (*Specification*, page 10, lines 10-12); an "implantable defibrillator with cardiac sensor" **90I** in **Figure 8** (*Specification*, page 10, lines 20-22); a "favorable cardiac compression timing module" **450** in **Figure 10** (*Specification*, page 13, line 5-8)); and means for compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac cycle based on the identified time (block **134**, **Figure 3**, (*Specification*, page 9, lines 11-20); a "mechanical compression device" **40** in **Figures 4A, 5A** (*Specification*, page 9, lines 8-10 and 19-20); an "automated mechanical compression device" **420** in **Figure 10** (*Specification*, page 13, lines 20-21)).

The independent Claim 42 recites a system for assisting in chest compression in a subject having cardiomalfunction. The system includes at least one cardiac activity sensor (*e.g.*, "cardiac activity sensor" **30** in **Figures 6-7** and **9** (*Specification*, page 10, lines 10-12); an "implantable defibrillator with cardiac sensor" **90I** in **Figure 8** (*Specification*, page 10, lines 20-22)) in communication with the heart of a subject configured to detect a cardiac activity parameter and a controller (*e.g.*, a "controller" **40** in **Figures 4A-4B, 5A-5B** and **9** (*Specification*, page 9, lines 2-3) in communication with the at least one cardiac activity sensor. In operation, the at least one cardiac activity sensor transmits data to the controller regarding a spontaneous intrinsic cardiac cycle of the subject (*Specification*, page 9, lines 5-8 and lines 10-14) and the controller identifies a favorable time to deliver a chest compression based on the transmitted sensor data to avoid a vulnerable portion of the spontaneous intrinsic cardiac cycle (*Specification*, page 11, lines 1-3).

The independent Claim 49 recites a computer program product for timing the delivery of cardiac compression during CPR. The computer program product includes a computer readable storage medium having computer readable program code embodied in the medium. *Specification*, page 12, line 29 – page 14, line 28. The computer-readable program code includes computer readable program code that identifies a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject (block **130, Figure 3** (*Specification*, page 8, lines 9-11); a "favorable cardiac compression timing module" **450** in **Figure 10** (*Specification*, page 13, line 5-8)); and computer readable program code that determines a favorable time to deliver cardiac compression to a subject to avoid a vulnerable period of the spontaneous intrinsic cardiac cycle (blocks **132, 134, 136, Figure 3**, (*Specification*, page 8, lines 11-20); a "favorable cardiac compression timing module" **450** in **Figure 10** (*Specification*, page 13, line 5-8)).

Grounds of Rejection to be Reviewed on Appeal

Claims 26-28, 41-43, and 52 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,772,613 to Gelfand et al. ("Gelfand") in view of "Commotio cortis: sudden death due to chest wall impact in sports" by Link ("Link"). Claims 31-33, 44, 45, 52 and 54-57 stand finally rejected under 35 U.S.C. § 103(a) as being

unpatentable over Gelfand and Link in further review of U.S. Patent No. 6,390,996 to Halperin ("Halperin").

Argument

I. Introduction

To establish a *prima facie* case of obviousness, the prior art reference or references when combined must teach or suggest all of the recitations of the claim. M.P.E.P. § 2143. As recently affirmed by the United States Supreme Court in *KSR Int'l Co. v. Teleflex Inc*, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc*, 550 U.S. 1, 14 (2007) (citing *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006)). A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *Id.* at 15. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983); M.P.E.P. § 2146.

As discussed in more detail below, Appellants submit that the present rejections should be reversed because the cited prior art fails to teach or suggest all of the claim recitations, including: 1) identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject based on the sensed parameter and/or 2) compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac cycle based on the identifying step, thereby inhibiting reinduction of fibrillation and/or improving cardiac function as recited in the independent claims. In addition, there are no reasons to combine Gelfand and Link; moreover, the references teach away from their combination.

II. Claims 26-28, 41-43, and 52 are not obvious over Gelfand and Link.

Claim 26 recites a method for performing chest compression during cardiopulmonary resuscitation (CPR), including:

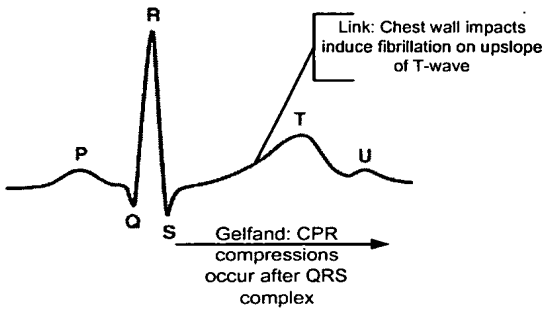
> sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR;
> identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject based on the sensed parameter; and

compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac cycle based on the identifying step thereby inhibiting reinduction of fibrillation and/or improving cardiac function.

The Examiner concedes that Gelfand does not disclose identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject and compressing the heart of the subject during a non-vulnerable portion based on the identifying step; however, the Examiner takes the position that Link discloses that chest impacts on the upslope of the T wave results in ventricular fibrillation. The Examiner concludes that it would have been obvious to combine Gelfand with Link to time the compressions to avoid the vulnerable "up-slope" T-wave portion of the cardiac cycle. *See* the Final Action, pages 3-4.

Appellants respectfully disagree. Notably, Gelfand proposes timing compressions so that they apparently coincide with the portion of the cardiac cycle (the upslope of the T wave) in Link that resulted in ventricular fibrillation. As such, Gelfand teaches away from avoiding chest wall compressions during this portion of the cardiac cycle. In addition, there are no reasons to combine the teaching of Link, which describes inducing ventricular fibrillation with chest wall impacts in healthy individuals, and the cardiopulmonary resuscitation (CPR) system of Gelfand.

In particular, Gelfand discusses in column 9, lines 5-10, that the timing of the inflation phase of the vest (corresponding to a compression of the heart) may be at "a predetermined time following the QRS complex wave of the ECG signal." In contrast, Link hypothesizes that ventricular fibrillation in healthy individuals may be caused by a chest wall impact during a vulnerable period of the cardiac cycle, *i.e.*, the upslope of the T-wave. Link, page 1, paragraph 2. As illustrated in the schematic diagram of an ECG below, Gelfand teaches test compressions that coincide with the chest wall impacts which caused fibrillation (the upslope of the T-wave) in Link.



Appellants note that the Advisory Action stated that portions of the ST segment occurs after the QRS complex, but before the upslope of the T-wave. *See* the Advisory Action, page 2. Appellants further note that the downslope of the T-wave and the U-wave also occur after the QRS complex. It may, therefore, be possible to apply a compression in the time period after the QRS complex according to the teachings of Gelfand that does not coincide with the upslope of the T-wave as noted in the Advisory Action. However, as can be seen in the schematic ECG signal above, the time period following the QRS complex, which is identified in Gelfand for chest compressions, also clearly coincides with the upslope of the T-wave portion of the cardiac cycle. In contrast to the teachings of Gelfand, Link discusses that chest wall impacts can induce fibrillation when the impact occurs on the upslope of the T-wave. Appellants submit that Gelfand teaches away from **avoiding** CPR compressions on the upslope of the T-wave portion of the cardiac cycle because Gelfand specifically identifies portions of the cardiac cycle, including the upslope of the T-wave, as a time period in which compressions should be applied.

In addition, there are no reasons to combine Link and Gelfand. Link is concerned with sudden death resulting from chest wall blows incurred by young, healthy people participating in sports such as hockey, lacrosse, softball and baseball. Link discusses that the victims of this condition have no known histories of heart disease or other chronic medical illness. Link, page 1, paragraphs 1-2. Link hypothesizes that ventricular fibrillation in healthy individuals may be caused by a chest wall impact during a vulnerable period of the cardiac cycle. Link, page 1, paragraph 2. In contrast, Gelfand proposes a cardiopulmonary resuscitation (CPR) system that is used on patients that are generally already experiencing ventricular fibrillation, or in individuals that have a beating, yet very weakened, heart. Gelfand, col. 1, lines 25-28 and col. 8, line 62 – col. 9, line 10.

Appellants submit that there are no reasons that that the findings of induced fibrillation in Link in healthy individuals should be applied to the application of CPR to sick patients experiencing ventricular fibrillation and/or a weakened heart as maintained by the Examiner. There is also no suggestion in the references that sick individuals would be just as vulnerable or more vulnerable to the induction of ventricular fibrillation as maintained in the Advisory Action on page 3. In particular, many of the patients in Gelfand are already experiencing ventricular fibrillation. Therefore, Appellants submit that there are no reasons

to combine the teachings of Link, which involve inducing ventricular fibrillation in healthy individuals, with the CPR device of Gelfand, which is used on sick patients who may already be experiencing ventricular fibrillation.

In summary, neither Gelfand nor Link teach or render obvious 1) identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject based on the sensed parameter and/or 2) compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac cycle based on the identifying step, thereby inhibiting reinduction of fibrillation and/or improving cardiac function, as recited in independent Claim 26. There are no reasons to combine the teachings of Link, which relate to inducing fibrillation in healthy individuals, with Gelfand, which is concerned with sick patients who may be experiencing ventricular fibrillation. Moreover, Gelfand proposes timing chest compressions that coincide with the portions of the cardiac cycle which Link proposes induce ventricular fibrillation, and, as such, Gelfand teaches away from a combination with Link.

Independent Claims 41, 42 and 49 include similar recitations to those emphasized with respect to independent Claim 26 for a system for performing chest compressions (Claims 41 and 42) and a computer program product for timing the delivery of chest compressions (Claim 49) and are also patentable over the cited art for at least the reasons discussed above. Claims 25-28, 42-43, and 52 depend directly or indirectly from independent Claims 26, 41, 42 or 49 and are patentable at least per the patentability of the claims from which they depend.

For at least the reasons discussed above, Appellants submit that Claims 26-28, 41-43, and 52 are not obvious over Gelfand and Link and request that the rejection be reversed.

III. Claims 31-33, 44, 45, 52 and 54-57 are not obvious over Gelfand, Link and Halperin

Claims 31-33, 44, 45, 52 and 54-57 depend directly or indirectly from independent Claims 26, 41, 42 or 49 and are patentable at least per the patentability of the claims from which they depend. The features discussed above are also not taught or suggested by Halperin (discussed on pages 5-7 of the Final Action as allegedly disclosing the use of closed chest manual compressions based on sensed ECG patterns).

For at least these reasons, Appellants submit that the rejections of Claims 31-33, 44, 45, 52 and 54-57 should be reversed.

CONCLUSION

In view of the above discussion, Appellants submit that the rejection of Claims 26-28, 31-33, 41-45, 49, 51, 52 and 54-57 should be reversed and the present application passed to issue.

Respectfully submitted,

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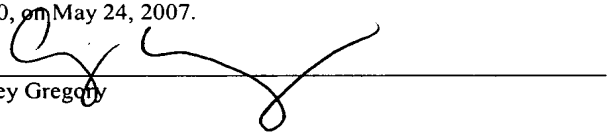

Carey Gregory

Claims Appendix

1-25 (Canceled)

26. (Previously Presented) A method for performing chest compression during cardiopulmonary resuscitation (CPR), comprising;

sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR;

identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject; and

compressing the heart of the subject during a non-vulnerable portion of the spontaneous intrinsic cardiac cycle based on the identifying step thereby inhibiting reinduction of fibrillation and/or improving cardiac function.

27. (Original) A method according to Claim 26, wherein the sensing is carried out in substantially real-time.

28. (Previously Presented) A method according to Claim 26, wherein the compressing step is initiated at a time that does not overlap with a T wave portion of the spontaneous intrinsic cardiac cycle.

29. (Withdrawn) A method according to Claim 26, wherein the sensing step is carried out using a sensing electrode in communication with an external defibrillator.

30. (Withdrawn) A method according to Claim 26, wherein the sensing step is carried out using an internal sensing electrode in communication with an implantable defibrillator.

31. (Original) A method according to Claim 26, wherein compressing the heart comprises manually compressing the heart.

32. (Original) A method according to Claim 31, further comprising automatically generating an audible alert when compression is to be initiated to direct a person to initiate manual compression.

33. (Original) A method according to Claim 31, wherein the manual compression is a closed chest manual compression.

34. (Withdrawn) A method according to Claim 31, wherein the manual compression is an internal chest compression.

35. (Withdrawn) A method according to Claim 31, wherein the manual compression is an open chest compression.

36. (Withdrawn) A method according to Claim 26, wherein compressing the heart comprises mechanically compressing the heart using a compression device.

37. (Withdrawn) A method according to Claim 26, further comprising automatically controlling the device to apply the mechanical compression based on the timing of the intrinsic cardiac cycle as determined by the sensed parameter.

38. (Withdrawn) A method according to Claim 37, wherein the device is an external device residing on a closed chest of the subject.

39. (Withdrawn) A method according to Claim 37, wherein the device comprises an internal portion that automatically inflates and deflates to provide a minimally invasive direct cardiac massage.

40. (Withdrawn) A method according to Claim 38, wherein the external device comprises an inflatable vest configured to compress the chest.

41. (Previously Presented) A system for performing chest compression during cardiopulmonary resuscitation (CPR), comprising;

means for sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR; and

means for electronically identifying a favorable time to compress the chest to avoid a vulnerable portion of a spontaneous intrinsic cardiac cycle of the subject based on the sensed parameter; and

means for compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac cycle based on the identified time.

42. (Previously Presented) A system for assisting in chest compression in a subject having cardiomalfunction, comprising:

at least one cardiac activity sensor in communication with the heart of a subject configured to detect a cardiac activity parameter; and

a controller in communication with the at least one cardiac activity sensor, wherein, in operation, the at least one cardiac activity sensor transmits data to the controller regarding a spontaneous intrinsic cardiac cycle of the subject and the controller identifies a favorable time to deliver a chest compression based on the transmitted sensor data to avoid a vulnerable portion of the spontaneous intrinsic cardiac cycle.

43. (Previously Presented) A system according to Claim 42, wherein the controller identifies a time that does not overlap with the T wave portion of the spontaneous intrinsic cardiac cycle.

44. (Original) A system according to claim 42, further comprising an audible alert in communication with the controller, the controller configured to output an audible alert signal responsive to an identified favorable time to deliver a chest compression to the subject based on the transmitted sensor data.

45. (Original) A system according to Claim 44, further comprising a power supply in communication with the controller and a display configured to display a spontaneous intrinsic cycle and visually indicate a favorable time to deliver a chest compression based on the transmitted sensor data.

46. (Withdrawn) A system according to Claim 42, further comprising a mechanical device configured to apply chest compression at selected intervals, the controller configured to automatically actively control the timing of the compression applied by the mechanical device.

47. (Withdrawn) A system according to Claim 46, wherein the mechanical device is an external compression device.

48. (Withdrawn) A system according to Claim 46, wherein the mechanical device comprises an internal compression device.

49. (Previously Presented) A computer program product for timing the delivery of cardiac compression during CPR, the computer program product comprising:

a computer readable storage medium having computer readable program code embodied in said medium, said computer-readable program code comprising:

computer readable program code that identifies a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject; and

computer readable program code that determines a favorable time to deliver cardiac compression to a subject to avoid a vulnerable period of the spontaneous intrinsic cardiac cycle.

50. (Withdrawn) A computer program product according to Claim 49, further comprising computer readable program code that identifies when electrical stimulation is applied to the subject, wherein the computer readable program code that determines the favorable time is based on the time that the electrical stimulation is applied.

51. (Previously Presented) A computer program product according to Claim 49, further comprising computer readable program code that receives data corresponding to the spontaneous cardiac activity of the subject in substantially real time, wherein the computer readable program code that determines the favorable time is based on the identified vulnerable portion of the cardiac cycle and the received data.

52. (Original) A computer program product according to Claim 49, further comprising computer readable program code that outputs an audible alert when a favorable cardiac compression time is determined.

53. (Withdrawn) A computer program product according to Claim 52, further comprising computer readable program code that automatically directs the activation of a mechanical compression device in response to the determined favorable time.

54. (Previously Presented) A method according to Claim 26, further comprising audibly alerting when to start the compressing and when to stop the compressing based on the identifying step.

55. (Previously Presented) A system according to Claim 41, wherein the means for electronically identifying a favorable time to compress the chest is configured to audibly generate when to start compression and when to stop compression to avoid a vulnerable portion of a spontaneous intrinsic cardiac cycle of the subject.

56. (Previously Presented) A system according to Claim 42, further comprising an audio alert in communication with the controller wherein, in operation, the audio alert is configured to signal when to start compression and when to stop compression to avoid the vulnerable portion of the spontaneous intrinsic cardiac cycle.

57. (Previously Presented) A computer program product according to Claim 52, further comprising computer readable program code that outputs an audible alert when to stop compression to avoid an unfavorable cardiac compression time.

58. (Withdrawn) A method according to Claim 26, further comprising applying an electrical stimulation within about 1 second of the compressing step.

59. (Withdrawn) A system according to Claim 42, further comprising an electrical stimulation source in communication with the controller, wherein the system is configured to apply electrical stimulation to the chest of the subject within about 1 second of the compression.

Evidence Appendix

None.

Related Proceedings Appendix

NONE